**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License:** The Development of Human Anti-CD22 Monoclonal Antibodies for the Treatment of Human Cancers and Autoimmune Disease

**AGENCY:** National Institutes of Health, Public Health Service, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in U.S. Patent Application 61/042,239 entitled "Human Monoclonal Antibodies Specific for CD22" [HHS Ref. E-080-2008/0-US-01], PCT Application PCT/US2009/124109 entitled "Human and Improved Murine Monoclonal Antibodies Against CD22" [HHS Ref. E-080-2008/0-PCT-02], US patent application 12/934,214 entitled "Human Monoclonal Antibodies Specific for CD22 " [HHS Ref. E-080-2008/0-US-03], and all related continuing and foreign patents/patent applications for the technology family, to Sanomab, Ltd. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

> The use of the m971 and m972 (SMB-002) monoclonal antibodies as therapies for the treatment of B cell cancers and autoimmune disease. The Licensed Field

of Use includes the use of the antibodies in the form of an immunoconjugate, including immunotoxins.

Upon the expiration or termination of the exclusive evaluation option license, Sanomab, Ltd. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

**DATE:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: lambertsond@od.nih.gov.

**SUPPLEMENTARY INFORMATION:** This invention concerns monoclonal antibodies against CD22 and methods of using the antibodies for the treatment of CD22-expressing cancers, including hematological malignancies such as hairy cell leukemia, chronic lymphocytic leukemia and pediatric acute lymphoblastic leukemia, and autoimmune disease such as lupus and Sjogren's syndrome. The specific antibodies covered by this technology are designated m971 and m972 (SMB-002; applicant designation).

CD22 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, and is involved in the modulation of the immune system. The m971 and m972 antibodies

can selectively bind to diseased cells and induce cell death while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

February 13, 2012
Date

Richard U. Rodriguez,
Director
Division of Technology Development & Transfer
Office of Technology Transfer
National Institutes of Health

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